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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,842	04/29/1999	BRIAN C.A. FERNANDES	P0008383.00	6147

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/301,842	FERNANDES ET AL.	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36 and 41-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36 and 41-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42-44 depend from claim 40, which has been canceled and thus it is not clear as to what limitations are encompassed by these claims. (For examination purposes, Examiner will assume that these claims were meant to depend from claim 41.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 21, 22, 24-26, 28-30, 32, 34-36, 41, 42, 44-50, 52, 53, 56, 57, 59-67, 69, 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,895,419.

Applicant claims a heart valve prosthesis comprising a sewing ring comprising an annular support initially formed from a biostable polymer mixed with a therapeutic agent, said annular support overlaid by a polyester fabric overlay, wherein said annular support provides at least one therapeutic effect to the fabric overlayer.

Helmus disclose polymers which may be used in the formation of or the coating of medical devices which contact body various body tissues and bodily fluids such device being for example, artificial heart components, vascular grafts, heart valves among other things (col. 9, lines 52-68.)

It is also taught by Helmus that the articles might also be formed entirely from the release polymer, in which case, a prepolymer mixture including the desired quantity of heparin is prepared, formed into the desired shape and polymerized. A prepolymer solution containing an elutable component is next applied over the article and polymerized to form the surface-layer. Additionally, articles may be formed by thermal means such as injection molding a mixture of polymer and active agent. The outer layer may be formed by molding the polymer and elutable agent mixture around the body of the device by insert molding techniques (col. 9, lines 38-49.).

Thus, as to claims 21, 45, 46, 52 and 60, Helmus discloses an implantable medical device (see column 9, lines 52-68, disclosing a medical device such as artificial heart components) initially formed from a biostable polymer mixed with a

therapeutic agent (see col. 9, lines 38-49, disclosing that the medical device/article may be formed from a prepolymer mixture including the desired quantity of heparin is prepared or alternatively by injection modling a mixture of polymer and active agent), and wherein the medical device comprises a body portion overlaid by a fabric overlayer (see column 9, lines 38-48, disclosing a prepolymer solution containing an elutable component applied over the article and polymerized to form the surface-layer, or alternatively injection molding a mixture of polymer and elutable agent mixture around the body of the device by insert molding techniques), and wherein medical device provides at least one therapeutic effect to the fabric overlayer (see col. 9, 39-40, line 45-46, disclosing the therapeutic agent and col. 3, lines 34-47, and col. 6, lines 18-25, disclosing release of the therapeutic agent.)

However, Helmus does not specifically disclose an embodiment wherein such a medical device is annular.

Tweden discloses an annuloplasty ring (22) that includes an outer layer of fabric (24), such as a woven or knitted polyester, which may surround a frame (23), which may be flexible, and a polymer, such as silicone (see column 2, lines 45-50, and see column 3, lines 30-33.) Tweden also discloses that the devices could be coated with a therapeutic agent, (see column 2, lines 51-67, see also col. 3, lines 16-19, and col. 4, lines 20-22). Since Helmus discloses that the prepolymer mixture can be used to form various medical device such as artificial heart components and heart valves (col. 9, lines 52-68), the skilled artisan would have looked to the art, such as the Tweden patent, for such specific medical devices that can be formed according to the Helmus

teachings. It would have been obvious to one of ordinary skill in the art to use the Helmus teachings regarding the prepolymer mixture including therapeutic agent (and coating) to form the Tweden heart valve as the specific type of medical device generally disclosed by Helmus. That is, in combining the teachings of Helmus and Tweden, it would have been obvious to the skilled artisan that the Tweden heart valve can be alternatively formed such that the therapeutic materials are in the polymer or prepolymer mixture that forms the device, as taught by Helmus, rather than the therapeutic materials being coated on the device. The Tweden annuloplasty ring meets the annular limitation recited by Applicant.

As to claim 32, 50, 67, 69, 70 eparin is inherently an anti-inflammatory.

As to claims 34, 44, the therapeutic agent may be antimicrobial (see Helmus, col. 2, line 7.)

As to the following claims, Tweden discloses the limitations as follows.

As to claims 22, 30, 42, 47, 63, the polymer insert comprises silicone, see column 3, line 36-38.

As to claims 24, 28, 35, 36, Tweden discloses that the heart valve may be bioprosthetic or mechanical, see column 2, lines 3-6, and lines 30-35.

As to claims 25, 53, 57, 66, Tweden teaches a fabric of polyester, see column 2, lines 45-50, and see column 3, lines 30-33.

As to claims 26, 48, 49, 64, 65, the body portion additionally comprises a metal, see column 3, line 40.

As to claims 29, 60, 61,62, Tweden discloses that the heart valve comprises a polymer insert containing struts attached to tissue leaflets to form a valve housing, wherein a fabric sheath encloses the polymer insert to form sewing ring, see column 2, line 31.

As to claims 41, 56, Tweden discloses an annuloplasty ring (22). Also, as to claim 41, Tweden discloses the suture/sewing cuff or fabric as comprising a knitted or woven fabric of polyester (see column 2, lines 45-50, and see column 3, lines 30-33.) In combining the teachings of Tweden and Helmus as discussed above, the skilled artisan would utilize a prepolymers mixture to form a polymer (with therapeutic agent) such as polyester as disclosed by Tweden as the particular type of polymer in the Helmus invention.

As to claim 59, because the combination of the prior art as discussed above would result in the same invention as claimed by Applicant, it must have the same biological effect recited by Applicant.

2. Claims 23, 27, 33, 43, 51, 54, 58 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,895,419, and further in view of Fearnot et al., 5,609,629.

Helmus-in-view-of-Tweden disclose the invention substantially as claimed, (see above.) More specifically, Helmus discloses that the therapeutic agent comprises an anti-inflammatory agent, see column 2, line 6. Helmus also discloses that devices that could be coated with the therapeutic agents include vascular stents, see column 9, line

63. However, Helmus does not disclose the anti-inflammatory agent as being dexamethasone.

Fearnot teaches that dexamethasone or other anti-inflammatory agent can be coated on an implantable medical device for implantation into, for example, the vascular system (column 4, line 33) for delivery of the agent (col. 8, lines 46-47 and col. 8, line 66 – col. 9, line 2.) It would have been obvious to one of ordinary skill in the art at the time the invention was made, to apply a layer of dexamethasone, as taught by Fearnot, onto implantable medical devices as taught by Helmus-in-view-of-Tweden, since dexamethasone, being an anti-inflammatory, is disclosed by Fearnot as being a useful bioactive agent to be coated on an implantable medical device.

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3. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,895,419, as applied to claim 30 above, and further in view of Myers, 5,716,397.

Helmus-in-view-of-Tweden disclose the invention substantially as claimed, (see above.) It is noted that Tweden discloses an annuloplasty ring (22). However, neither Helmus nor Tweden does not disclose a polymer insert comprising radiopaque flexible silicone rubber.

Myers discloses an annuloplasty ring consisting of a soft core of silicone rubber impregnated with radiopaque salt (col. 1, lines 44-51 and col. 2, lines 46-50.) Myers teaches that it is desirable for the annuloplasty ring to be flexible once implanted (col. 2,

7-10.) The radiopacity allows the presence and functioning of the implant to be monitored after completion of the implant surgery (col. 2, lines 50-53.)

It would have been obvious to one of ordinary skill in the art combine the teachings of Helmus, Tweden and Myers such that the mixture of polymer (or prepolymer) with therapeutic agent also comprises silicone rubber and a radiopaque agent to form an annuloplasty ring that provides the benefit of flexibility and radiopacity for monitoring after implant surgery, as taught by Myers.

Response to Arguments

Applicant's arguments filed May 27, 2004 have been fully considered but they are not persuasive.

Applicant argues that using the teachings of Helmus and Tweden, the skilled artisan would coat or impregnate the fabric layer to protect the layer, which teaches away from the designing the device such that the component is *initially* formed from the polymer *mixed* with the therapeutic agent. Applicant assert that therefor there is no coating of the device but the device is formed from the device containing the polymer and therapeutic agent.

As noted above in the grounds for rejection, Helmus teaches that the articles might be formed entirely from the release polymer, in which case, a prepolymer mixture including the desired quantity of heparin is prepared, formed into the desired shape and polymerized (col. 9, lines 38-49.) A prepolymer solution containing an elutable

component is next applied over the article and polymerized to form the surface-layer. Thus, the medical device is formed from an initial prepolymer mixture with a therapeutic agent, and the surface-layer can likewise be formed from a prepolymer solution with an elutable component. Helmus also teaches that additionally, articles may be formed by thermal means such as injection molding a mixture of polymer and active agent. The outer layer may be formed by molding the polymer and elutable agent mixture around the body of the device by insert molding techniques (col. 9, lines 38-49.) In this case, the article is also formed from an initial mixture of polymer and active agent and the outer layer also formed from an initial mixture of polymer and elutable agent. Thus, contrary to Applicant's argument, the medical device and any coating can both be initially formed from a polymer mixed with a therapeutic agent. In combining the references, the skilled artisan would utilize such teachings of using a mixture of a polymer or prepolymer and a therapeutic agent to form the specific medical device suggested by the secondary references.

Applicant also argues that Applicant further specifies an annular polymer support of the sewing ring is formed with the therapeutic agent. Examiner notes that as stated in the grounds for rejection, Tweden discloses a suture/sewing cuff or fabric comprising a knitted or woven fabric of polyester, (see column 2, lines 45-50, and see column 3, lines 30-33). The Tweden sewing cuff is a sewing ring and thus meets Applicant's limitation.

The remainder of Applicant's argument essentially makes the same arguments that neither Helmus nor any of the cited references teach that the medical device is

initially formed from the polymer *mixed* with the therapeutic agent. These arguments are not persuasive for the same reasons as discussed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641